



**JAPAN SOCIETY OF PHARMACEUTICAL
MACHINERY AND ENGINEERING**

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October 3, 2005

**Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
U.S.A.**

Re: Docket No. 2005D-0288

Dear Sir/Madam:

We, the Japan Society of Pharmaceutical Machinery and Engineering (JSPME) are pleased to submit you our offers and comments concerning "International Conference on Harmonisation; Draft Guidance on Q9 Quality Risk Management" (Docket No. 2005D-0288). We hope that you will consider our comments, and this guidance will be a very fruitful guidance for assuring product quality and ensuring risk management.

We would be much obliged if you give us FDA review of our comments by letter or e-mail.

Contacts;

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Sincerely,

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